

K122487

**510(k) Summary**

SEP 17 2012

**Tornier Inc. BioFiber Suture**

**Date prepared: September 13, 2012**

**Regulatory authority: Safe Medical Devices Act of 1990, 21 CFR 807.92**

**1) Device name**

**Trade name:**

BioFiber Suture

**Common name:**

Suture, recombinant technology

**Classification Number/ Classification name/Product code:**

Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology are class II devices under 21 CFR § 878.4494 (product code NWJ) and are classified by the General and Plastic Surgery Devices Panel.

**2) Submitter**

Tornier, Inc.  
10801 Nesbitt Avenue  
Bloomington, MN 55437  
Registration Number: 9100540

**3) Company contact**

Lael J. Pickett  
Regulatory Affairs  
Tornier, Inc.  
10801 Nesbitt Avenue  
Bloomington, MN 55437 USA  
Telephone: 612-219-7350/Fax: 952-426-7601  
Email: lpickett@tornier.com

**4) Classification**

**Device class:**

Class II

**Classification panel:**

General and Plastic Surgery Devices

**Product code:**

NWJ

**Special Controls:**

Class II Special Controls Guidance Document: Absorbable Poly(hydroxybutyrate) Surgical

Suture Produced by Recombinant DNA Technology

**5) Legally Marketed Device to which Equivalence is Claimed:**

TephaFLEX™ Poly(4-hydroxybutyrate) Suture: (K052225, K081099 and K082178)

**6) Comparison to Predicate Devices**

<b>Feature</b>	<b>From:</b> TephaFLEX poly(4-hydroxybutyrate) suture (K052225, K081099 & K082178)	<b>To:</b> Tornier BioFiber Suture (K122487))
<b>Indications for Use</b>	For use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.	Same.
<b>Design</b>		
<b>Composition</b>	P4HB	Same
<b>Needles attached</b>	Available with and without needles attached	Same
<b>USP Size</b>	Size 0	Size 2
<b>Design</b>	Monofilament	Braided
<b>Colors</b>	Un-dyed (natural) or dyed (violet)	Same
<b>Performance</b>		
<b>USP &lt;861&gt; Suture diameter</b>	Compliant for size 0	Compliant for Size 2, except that the diameter is slightly larger
<b>USP &lt;871&gt; Suture Needle Attachment</b>	Compliant for size 0	Compliant for Size 2
<b>USP &lt;881&gt; Tensile Strength</b>	Compliant for size 0	Compliant for Size 2

**7) Device description**

Tornier, Inc. BioFiber Suture is an absorbable, braided, sterile, surgical suture composed of poly(4-hydroxybutyrate) (P4HB). BioFiber Suture is braided for optimal handling properties and is available either dyed (D&C Violet No. 2)<sup>1</sup> or un-dyed (natural), with and without pre-attached needles.

**8) Indications for Use**

BioFiber Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

**9) Summary of technologies**

Testing was performed in accordance with FDA's *Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology*. This testing included mechanical testing in accordance with USP requirements for absorbable surgical suture (strength, knot break, needle attachment strength) and USP suture diameter measurements. Additionally, ISO 10993-1 testing for permanent implant materials was performed, as well as resorption/degradation testing and packaging evaluation.. The results of this non-clinical

<sup>1</sup> 21 CFR § 74.3602 D&C Violet No. 2.

testing allow us to conclude that the BioFiber Suture described in this submission is substantially equivalent and as safe and effective as the predicate device.



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Tornier, Incorporated  
% Ms. Lael J. Pickett  
Regulatory Affairs  
10801 Nesbitt Avenue  
Bloomington, Minnesota 55437

SEP 17 2012

Re: K122487

Trade/Device Name: BioFiber® Suture  
Regulation Number: 21 CFR 878.4494

Regulation Name: Absorbable poly (hydroxybutyrate) surgical suture produced by  
recombinant DNA technology

Regulatory Class: Class II  
Product Code: NWJ  
Dated: August 9, 2012  
Received: August 15, 2012

Dear Ms. Pickett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

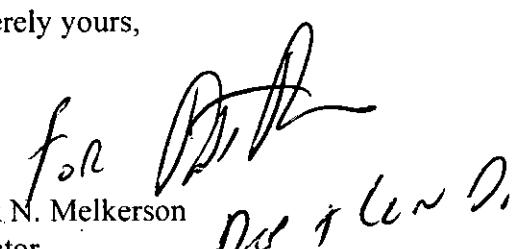
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known):

Device Name: **Tornier, Inc. BioFiber® Suture**

## Indications for Use

BioFiber Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)  
Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K12248